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INFORMATION DISCLOSURE

STATEMENT BY ARPLICANT

(use as many sheets as necessary)

of

Complete if Known				
Application Number	09/393,590			
Filing Date	09/09/1999			
First Named Inventor	MOYER, Elizabeth			
Group Art Unit	1645			
Examiner Name	S. Devi			
Attorney Docket Number	211-US-NEW			

				U.S. PATENT DOC	UMENTS	
Examiner Initials*	Cite No.1	Number	ocument Kind Code ² (<i>if known</i>)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
58	AA	5,721,215		Aoki, K.R. et al.	02/24/1998	\
48	AB	5,053,005		Borodic, G.E. et al.	10/01/1991	
49	AC	4,932,936		Dykstra, D.D. et al.	06/12/1990	
48	AD	5,696,077		Johnson, E.A. et al.	12/09/1997	
48	AE	5,437,291		Pasricha, P.J. et al.	08/01/1995	
49	AF	5,512,547		Johnson, E.A. et al.	04/30/1996	
48	AG	5,766,605		Sanders, I. et al.	06/16/1998	
49	AH	5,183,462		Borodic, G.E.	02/02/93	
99	AI_	5,562,899		Gerber, A.	10/08/96	
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			FC	REIGN PATENT DOCUMEN	rs		
Examiner Cite Initials No.		Foreign Pa	tent Document Kind Coc er4 (if known	T Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
48	BA	WO 95/0	5842	Johns Hopkins Univ	03/02/1995		
9 9	BB	WO 93/0	5800	Allergan Inc.	04/01/1993		
47	BC	WO 96/3	9167	Pearce, B.L.	12/12/1996		
	BD	WO 94/0	0481	Associated Synapse	01/06/1994		
				Biologics			<u> </u>
40	BE	WO 97/3	5604	Wisconsin Alumni	10/02/1997		<u> </u>
				Research Foundation			<u> </u>
GR	BF	WO 96/1	1699	Wisconsin Alumni	04/25/1996		
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Cite No.1	U.S. Patent		U.S. PATENT DOC		Pages Columns Lines	
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537	BG	0 593 176 A2		Wisconsin Alumni	09/28/1992		
				Research Foundation			
98	BH	WO 95/17904		Allergan, Inc.	07/06/1993		
47	BI	WO 95/17904		Allergan, Inc.	07/06/1995		
58	BJ	WO 94/28923		Allergan, Inc.	12/22/1994		
48	BK	WO 94/28922		Allergan, Inc.	12/22/1994		
5 7	BL	WO 95/28171		Mt. Sinai School of Medicine	10/26/1995		
60	BM	WO 95/17904		Allergan, Inc.	07/06/1995		
	BN	WO 95/30431		Binder, W.J.	11/16/1995		
50	BO	WO 96/39167		Pearce, B.L.	123/12/1996		

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INFORMATION DISCLOSURE

RADEN Complete if Known 09/393,590 Application Number 09/09/1999 Filing Date Elizabeth MOYER STATEMENT BY APPLICANT First Named Inventor 1645 Group Art Unit **Examiner Name** S. Devi (use as many sheets as necessary) Attorney Docket Number of |2 Sheet 211-US-NEW

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
99	CA	FIRST, E.R., ET AL., "Dose Standardisation of Botulinum Toxin," The Lancet, vol. 343. p. 1035, (April 23, 1994).	
579	СВ	GARTLAN, M.G., ET AL., "Crystalline preparation of botulinum toxin type A (Botox): Degradation in potency with storage," Otolaryngology, vol. 108, p. 135-140, (1993).	
97	СС	HAMBLETON, B.C., ET AL., "Production, Purification and Toxoiding of Clostridium Botulinum Type A Toxin," Biomedical Aspects of Botulism, Acacemic Press (US), p. 247-260, (1981).	
47	CD	KADIS, S., ET AL., "Microbial Toxins," Bacterial Protein Toxins, Academic Press (US), p. 1-68, (1971).	
59	CE	LAMANNA, C., ET AL., "The Isolation of Type B Botulinum Toxin," Journal of Bacteriology, (US), vol. 54, p. 575-584, (1947).	
97	CF	MELLING, J., ET AL., "Clostridium Botulinum Toxins: Nature and Preparation for Clinical Use," Eye, vol. 2, p. 16-23, (1988).	
57	CG	SCHANTZ, E.J., ET AL., "Microbiological Methods," Journal of the AOAC (UK), Association of Official Analytical Chemists, Vol. 61 (No. 1), p. 96-99, (1978).	
9	СН	SCHANTZ, E.J., ET AL., "Quality of Botulinum Toxin For Human Treatment," Botulinum and Tetanus Neurotoxins, B.R. Dasgupta, ed., Plenum Press, p. 657-659, (1993).	
97)	CI	SLOOP, R.R., MD, ET AL., "Human response to botulinum toxin injection: Type B compared with type A,", The American Academy of Neurology (US), vol. 49, p. 189-194, (July 27, 1997).	
97	CJ	SUGII, S., ET AL., "Correlation Between Oral Toxicity and In Vitro Stability of Clostridium botulinum Type A and B Toxins of Different Molecular Sizes," Infection and Immunity, American Society of Microbiology (US), vol. 16, p. 910-914, (1977).	
97	CK	WRIGHT, G.P., "The Neurotoxins of Clostridium Botulinum and Clostridium Tetani," Pharmacology, vol. 7, p. 413-465, (1955).	

Examiner Signature	48	Date Considered	ood bolowo

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMA	TION DISCLO	SURE Filing	Date	09/09/1999	
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OTATEME			Art Unit	1645	
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Sheet 2	of 2	Attorne	ey Docket Number	211-US-NEW	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
59	CL	SCHANTZ, E.J., ET AL., "Dose standardisation of botulinum toxin," The Lancet, vol. 335, p. 421, (1994).				
577	СМ	TSUI, J.K.C., ET AL., "Botulinum toxin type B in the treatment of cervical dystonia: A pilot study," Neurology, vol. 45, p. 2109-2110, (1995).				
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considered. Include copy of this form with next communication to applicant.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

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STATEMENT BY APPLICANT				First Named Inventor	Elizabeth MOYER		
				Group Art Unit	1645		
	(use as many sheets as necessary)			Examiner Name	S. Devi		
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AUG 2 1 ZU	#9457	СМ	MOYER, E.D. ET AL., "Effects of Intramuscular Injection of Botulinum Toxin Type B in Nonhuman Primates," Botulinum and Tetanus Neurotoxins, Plenum Press (US), p. 655-656, (1993).	
	579	CN	LEW, M.F. ET AL., "Botulinum toxin type B: A double-blind, placebo-controlled, safety and efficacy study in cervical dystonia" Neurology (US), vol. 49, p. 701-707, (1997).	
	57	СО	PREVOT, A.R. ET AL., "New Studies on Botulism and its Five Toxin Types," Annals of the Pasteur Institute (FR), vol 85, p. 2-20, (1953).	
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